4.2 Provisional Guidance for the Outline of the SIDS Initial Assessment Report *

4.2.1 General aspects

1. The purpose of this document is to provide guidance on the nature, structure and format of the SIDS Initial Assessment Reports (SIARs). Such reports are to be prepared by the Sponsor countries and circulated to the SIDS Contact Points in a prompt manner to ensure their readiness for discussion at the SIDS Initial Assessment Meeting (SIAM).

2. The structure of the SIDS Initial Assessment Report should be such that it can be readily discussed at the SIDS Initial Assessment Meeting, and can provide assistance in drawing conclusions related to the potential risk of the chemical and priority for further work or action. With this in mind, it would be convenient if all such reports followed the same format and structure thus allowing quick and efficient references to be made. It would also enable the same types of information to be found in the same place in each report.

3. At the same time, harmonisation of assessment methods and contents of assessment reports is recommended in order that the same conclusions are made when similar data sets are reviewed and to make reports more comprehensible and usable to all Member countries. This document provides a model for harmonization of the structure and content of assessment reports.

4. Where an assessment report on a chemical has already been produced for a national or regional programme, it should be used to the extent possible, despite differences in structure to that proposed here, in order to avoid duplication of work. From this point of view, flexibility on minor issues, e.g. headings, is acceptable if the overall structure and content of the assessment report follow the guidance set out below.

4.2.2 Documents to be prepared

5. Documents to be submitted to the SIDS Initial Assessment Meeting, i.e. previously circulated to the SIDS Contact Points and the Secretariat, consist of the following:

- Cover page;
- SIDS Initial Assessment Profile;
- Full SIDS Summary; and
- SIDS Initial Assessment Report with Full SIDS Dossier

6. The cover page (the format is shown in Annex 2 to this guidance) reviews the decisions taken in the SIDS Review process regarding SIDS testing to be undertaken and briefly describes the history of the chemical in the programme to date.

7. The SIDS Initial Assessment Profile which follows the cover page (the format is shown in Annex 3 to this guidance) summarises the conclusions of the initial assessment and recommendations based on them by the Sponsor country. Conclusions include the summary of properties and effects of the chemical and the result of the assessment on potential risk to man and the environment. Recommendations relate to the need for further work or action on the chemical. The reasons which support the recommendations, including those related to risk reduction measures or safe handling procedures in Member countries, should be given. Proposals for Post-SIDS work or in-depth risk assessment, or further action in the area of risk management, as appropriate, should also be described. This profile is similar to Chapter 5 of the assessment report shown in Annex 1 to this guidance.

8. The full SIDS Summary (the format is shown in Annex 4 to this guidance) will help readers understand the properties and effects of the chemical. Although it may repeat information later contained in the assessment report and the Full SIDS Dossier, this table is meant to allow a quick review of the data (e.g. properties, exposure and effects). Data beyond SIDS requirements can be added if the items are relevant to the assessment of the chemical, e.g. corrosiveness/irritation, carcinogenicity.

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* This document was prepared by the OECD Secretariat based on the agreements reached in the OECD Existing Chemicals Programme up to May 1996. This guidance should be applied to the assessment reports prepared for the 4th SIAM and thereafter.

4.2.3 Full SIDS Dossier

9. The Full SIDS Dossier, including information additional to the SIDS requirements, if available, should be annexed to the SIDS Initial Assessment Report.

10. In order to avoid duplicative work, it is assumed that the original SIDS Dossier prepared by the Sponsor country and reviewed in the SIDS Review Process will form the basis for the SIDS Initial Assessment Report. This original SIDS Dossier may have to be updated by the Sponsor country to become a Full SIDS Dossier, i.e. inclusion of the results of the SIDS tests which have been carried out and any new information obtained, particularly with regard to exposure and use. Full reports of the SIDS testing do not need to be attached, but they should be available on request.

11. The data elements in the original SIDS Dossier for which no SIDS tests had been requested are normally considered to be of adequate quality, and can be used as a basis for making an initial assessment. In some cases, the content of the data elements in the original SIDS Dossier might be reviewed, taking into account the "Quality of and Access to Data Used to Prepare SIDS Dossiers" (see Section 3.2) and the comments by Member countries through the SIDS Review process. The validated data should clearly be identified in the SIDS Dossier as "preferred results" (see also Section 2.4, and Annex 2 to this Manual; Model SIDS Dossier).

12. The Full SIDS Dossier, as well as the original SIDS Dossier, should, if possible, be submitted with data on a HEDSET diskette, an export file from the IUCLID, or their print file.

4.2.4 SIDS Initial Assessment Report

13. The SIDS Initial Assessment Report should include:

- chemical identification, physical/chemical properties and information on classification and safe handling procedures (if appropriate);
- assessments of environmental exposure and ecotoxicity data;
- assessments of human exposure and toxicity data;
- comparison of the results of the exposure and effects assessments for the environment and human health respectively; and
- conclusions, and recommendations related to the potential risk and follow-up work or action if any are considered necessary.

14. The SIDS Initial Assessment Report should be a "stand alone" document. Therefore, the Report should also include, in each relevant section, a short self-explanatory summary of the data; for specific details, cross-reference should be made to the Full SIDS Dossier which is annexed. The data used for developing an assessment report should be examined carefully, especially for those chemicals which have a great deal of data. The key elements for the data evaluation are shown in "Considerations Concerning the Adequacy of Data in the SIDS", Section 3.5 of this Manual. Finally, only the validated data, i.e. preferred results, should be introduced in the assessment report and used for the assessment.

15. It is also very important to clearly identify which models, factors, assumptions, etc. have been used in making the initial assessments, in order to allow others to understand the reasons (and the uncertainties associated with them) behind the conclusions and recommendations.

16. An outline of the proposed structure and content of the SIDS Initial Assessment Report is set out in Annex 1 to this document. The structure has been modified from that used for reports up to and including the 3rd SIAM. This is because experience in the SIDS Programme has shown that it may be more appropriate to discuss exposure and effects for the environment and for human health separately, rather than to deal with all exposure situations and types of effects, respectively.

17. The length of the assessment report will depend upon the chemical being considered. A great deal of data related to different endpoints may be available for some chemicals, while only limited data on basic endpoints may be available for others. In both cases, however, the reports should generally be less than about 15 pages, in order to focus the discussion in the assessment meeting. Detailed information on the process and the results of assessment, e.g. on the estimation of environmental concentrations, can be added as an annex, where required.

18. At the 3rd SIAM held in Williamsburg, Virginia, in February 1995, participants agreed that the SIARs on Triethanolamine and Diethanolamine developed by UK were good models for the preparation of SIARs, though they were written according to the former structure.

19. The SIDS Initial Assessment Profile and Initial Assessment Report along with the Full SIDS Dossier will be published and made available world-wide through IRPTC.

4.2.5 Use of Guidance Materials

20. The following provisional guidance documents (also included in this manual) are available from the SIDS Contact Points:

- Initial Assessment of Environmental Exposure (Section 4.3);
- Initial Assessment of Occupational and Consumer Exposure (Section 4.4);
- Initial Assessment of Aquatic Effects (Section 4.5); and
- Initial Assessment of Health Effects (Section 4.6).

21. These guidance documents have been developed based on discussions among many experts from Member countries, the European Commission, IPCS and other bodies, at the OECD workshops on assessment, in the Hazard Assessment Advisory Body and in the Steering Group on Existing Chemicals. The intention of these guidance documents is to ensure that Sponsor countries have a common approach in developing their SIDS Initial Assessment Reports.

22. These guidance documents provide the "state-of-the-art" in each area, i.e. several methods, models, factors, assumptions, etc, which are used in some Member countries are introduced. They are intended to be used in the spirit of "learning by doing". Therefore, it would be very helpful if the Sponsor countries could indicate in their reports where they used methods other than those suggested in the provisional guidance and, in such cases, why.

23. These guidance documents will be reviewed regularly in order to evaluate their usefulness, to identify commonalities in approaches, and to make suggestions for further improvements and harmonization. In the long term, harmonisation of assessment methods is the goal.

4.2.6 Discussion at the SIDS Initial Assessment Meeting

24. Each SIDS Initial Assessment Report is circulated by the Sponsor countries to all SIDS Contact Points and the OECD Secretariat and is then discussed at the SIDS Initial Assessment Meeting. The purpose of the SIDS Initial Assessment Meeting is to reach consensus on the initial assessments and the conclusions and recommendations.

25. Based on an initial assessment of the effects and exposure data provided in the SIDS Dossier, each chemical can be described in light of the potential it presents for risk to man and/or the environment (including the extent of exposure and current risk reduction measures) and of the need for further work or action (e.g. post-SIDS testing, exposure analysis, in-depth risk assessment, further risk management action). Given the various possible combinations, conclusions and recommendations could be written, for example, as follows:

- The chemical can be considered to present a low potential for risk to man and the environment. Thus, there is no current priority for undertaking post-SIDS testing and/or exposure analysis or an in-depth assessment;

- The chemical may present a potential for risk to man and/or the environment. Thus, there is a priority for undertaking post-SIDS testing and/or exposure analysis and/or an in-depth assessment to clarify the nature or extent of the potential risk;

- The chemical presents a potential for risk to man and/or the environment. However, risk reduction measures currently in place in Member countries are considered adequate to control the risk. Thus, there is no current priority for further risk management action;

- The chemical presents a potential for risk to man and/or the environment. Due to the exposure and/or lack of current risk reduction measures, risk management actions might be necessary. These could range, as

appropriate, from responsible care activities by the chemical industry to national or international risk reduction activities;

- Etc.

26. The hazard(s) should be identified in the conclusions and specific further work or action to be undertaken should be proposed in the recommendations by the Sponsor country. Information on risk reduction measures in Member countries (e.g. classification, safe handling procedures, etc.) should also be included in the report, if relevant. These issues would be discussed and clarified at the SIAM and reviewed by the Steering Group and, subsequently, by the Joint Meeting.

27. It is conceivable that a chemical could be considered to present a potential risk based on a specific hazard and that there could also be a priority for further activities to clarify other potential effects (e.g. a chemical which is clearly genotoxic but on which further testing is required to clarify aquatic effects).

28. For those chemicals for which post-SIDS work and/or the in-depth risk assessment is recommended, the SIAM has to discuss the following issues:

- the rationale for and nature of further work needed to be done;
- the relative priority of this work;
- the provisional time schedule; and
- a country to oversee the work done by industry, etc. (see Chapter 5 of this Manual)

29. For those chemicals which present a potential for risk and for which further risk management actions are considered necessary, more discussion on the rationale for further risk management actions etc. based on information on current risk management of the chemical will be had in the Steering Group and, if needed, also at another forum in the OECD.

Annex 1

PROPOSED STRUCTURE AND CONTENT OF THE SIDS INITIAL ASSESSMENT REPORT

0. COVER PAGE
SIDS INITIAL ASSESSMENT PROFILE
FULL SIDS SUMMARY

See Annex 2, 3 and 4 to this guidance.

1. IDENTITY

This chapter should include the following basic information on the chemical:

- identification of the chemical (e.g. CAS Number, name, molecular formula, etc.)
- composition (e.g. degree of purity, impurities or additives, difference of purities among products)
- basic elements of physical-chemical properties (e.g. water solubility, P_{ow}, vapour pressure, etc.)
- classification used in Member countries, if appropriate

It may also suggest similar or analogous chemicals for which data is readily available and with which the SIDS chemical under consideration could be compared.

2. GENERAL INFORMATION ON EXPOSURE

General information on exposure should be summarised for the clear understanding of the exposure scenario described in Chapter 3, e.g.:

- production volume
- uses and functions
- form of marketed product(s)
- source(s) of release to the environment
- information on safe handling procedures (e.g. MSDS), if appropriate

Exposure situations in the Sponsor country and in other countries should be described.

3. ENVIRONMENT

3.1 Environmental Exposure

3.1.1 General Discussion

Based on the information on exposure, use pattern and physical-chemical properties, environmental fate and pathways are qualitatively discussed.

The description here also includes discussion on:

- fate in waste water treatment plants (WWTP), if relevant;
- distribution in air, water, soil etc.;
- abiotic and biotic degradation in air, water, soil;
- bioaccumulation in different environmental compartments; and
- possibility to form degradation products and their environmental fate and pathways.

Environmental compartments to be discussed in the exposure assessment should be identified following an analysis of release and accumulation.

3.1.2 Predicted Environmental Concentration

If quantitative analysis is possible, Predicted Environmental Concentrations (PECs) should be derived based on monitoring data and/or calculation by using exposure models. Estimation includes two approaches depending on the reliability of data;

- based on monitoring data and supported by calculation using models (to be preferred); or
- based on calculation using models and supported, if possible, by monitoring data.

When an exposure model is used, the frame and key parameters should be summarised here or attached as an annex.

At a minimum, $PEC_{regional\ (global)}$ and PEC_{local} in the aquatic compartment should both be derived. Monitoring data should be allocated to either regional (global) or local levels. PECs in other compartments (i.e. sediment, soil, air) may be derived and discussed depending on the exposure scenario.

If a quantitative analysis is not possible, a qualitative evaluation using use pattern and other information on physical-chemical properties and exposure may be given.

3.2 Effects on the Environment

3.2.1 Aquatic effects

Results of ecotoxicity tests are introduced and discussed, i.e.:

- acute (short-term) toxicity to fish, *Daphnia* and algae;
- available subchronic/chronic (prolonged/long-term) toxicity data on fish, *Daphnia* and algae; and
- other ecotoxicity data available.

Qualitative considerations are also to be mentioned concerning:

- the toxic mode of action of the chemical; and
- possibility to cause chronic effects based on physical-chemical properties, stability, relationship between acute toxicity and time, release pattern, degradation products, etc.

Finally, the Predicted No Effect Concentration (PNEC) value for the aquatic environment is derived by applying relevant assessment factors. The reasons for choosing these factors should be stated.

3.2.2 Terrestrial effects

If significant exposure to the terrestrial environment is expected, effects assessment for the terrestrial environment should be considered.

3.2.3 Other effects

Other ecotoxicological information that is available should also be taken into account and discussed depending on the exposure scenario and the reliability of the methods for effect assessments (e.g. "secondary poisoning", effects on sediment-dwelling organisms, effects on micro-organisms in WWTP, effects on the atmosphere). If there is a bioaccumulation potential, the discussion on the possibility of adverse effects due to "secondary poisoning" is recommended to be included.

If a quantitative analysis is not possible (e.g. chemicals difficult to test or unstable), a qualitative evaluation based on physical-chemical properties and estimation from analogues can be given.

3.3 Initial Assessment for the Environment

This includes a comparison of exposure assessments and effects assessment. The discussion on each environmental compartment should be described in separate subsections (i.e. 3.3.1 Aquatic compartment, 3.3.2 Terrestrial compartment, etc.).

If a quantitative analysis is possible, the PEC/PNEC ratio is calculated for each relevant environmental compartment.

- If PEC/PNEC $\geq$ 1, a specific hazard is or may be posed and Post SIDS work or other further activities should be considered.
- If PEC/PNEC < 1, a hazard cannot be identified and the chemical can be considered to present a low potential for risk to the environment. (If PEC/PNEC < 1 but near 1, the uncertainty of exposure assessment and effect assessment should carefully be examined. If there is a great degree of uncertainty, refinement of the initial assessment is recommended as further work.)

If a quantitative analysis is not possible, a qualitative evaluation by estimation based on exposure and effects information can be given.

4. HUMAN HEALTH

4.1 Human Exposure

Based on the information on exposure, use pattern and physical-chemical properties, the human populations on which the exposure assessment should be focused are identified. The exposure level for each population is then discussed.

4.1.1 Occupational exposure

Occupational exposure situations are discussed and, if appropriate, the Estimated Human Exposure (EHE) value is derived taking into account any measured data available and/or estimation by using models. Workplace exposure limit values (e.g. TLV, MAK) already determined should be introduced here.

4.1.2 Consumer exposure

Possibilities for consumer exposure are discussed and, if appropriate, the EHE is calculated by using exposure models.

4.1.3 Indirect exposure via the environment

Based on the discussion about the environmental exposure assessment, the possibility of indirect human exposure (via food, water and air) is discussed and, if appropriate, the EHE is calculated taking into account the monitoring data on fish and mammals or estimation by using models.

4.2 Effects on Human Health

Results of toxicity tests and other information are introduced and discussed, i.e.:

a) mode of action of the chemical, toxicokinetics and metabolism
b) acute toxicity;
c) repeated dose toxicity;
d) reproduction/developmental toxicity;
e) genetic toxicity; and
f) any other human health related information that is available.

If human data are also available, they should be described separately from non-human data. Toxicological significance of breakdown products or metabolites should be discussed where necessary.

From the test results on repeated dose toxicity and reproduction/developmental toxicity, NOAELs are derived. Other toxicity data including test conditions should be carefully examined and discussed.

4.3 Initial Assessment for Human Health

This includes a comparison of exposure assessments and effects assessments. The routes of exposure resulting in toxicity and critical effects and target organs should be identified in order to clarify the use of selected NOAELs.

Finally hazards for different human population should be identified and described in separate subsections (i.e. 4.3.1 Workers, 4.3.2 Consumers and 4.3.3 Those exposed via the environment).

For repeated dose toxicity and reproduction/developmental toxicity, risk for human health is examined by comparing the EHE with the NOAEL form animal data or, if available, with actual human data.

- If the estimated exposure level for a specific human population is larger than the estimated effect level of concern, i.e. the EHE is larger than or equal to the NOAEL, a specific hazard may exist and post-SIDS work or other further activities should be considered.
- If the estimated exposure level is much smaller than the estimated effect level of concern, i.e. the EHE is much smaller than the NOAEL, a hazard cannot be identified and the chemical can be considered to present a low potential for risk to man.
- If the estimated exposure level is less than but close to the estimated effect level of concern, i.e. the "margin of safety" is not very large, the uncertainty of exposure assessment and effect assessment should carefully be examined. If there is a great degree of uncertainty, refinement of the initial assessment is recommended as further work.

For other toxicological endpoints, a qualitative evaluation can be given.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

Properties and effects of the chemical and the result of the initial assessment for the environment and human health on the potential risk are summarised in this section as the overall conclusions. If significant data gaps exist (e.g. lack of information on exposure), these should be identified.

5.2 Recommendations

The recommendations by the Sponsor country are related to the need for further work or action (e.g. post-SIDS testing, exposure analysis, in-depth risk assessment, further risk management action) based on the conclusions. The reasons which support the recommendations, including a summary of risk reduction measures or safe handling procedures in Member countries, are given.

If post-SIDS work, or other further work or action is recommended, specific proposals should also be given.

6. REFERENCES

References not included in the Full SIDS Dossier should be described. References on key information could also be introduced here even if they are duplicated with those shown in the Full SIDS Dossier.

ANNEX : Full SIDS Dossier

See Chapter 2 and Annex 2 of this Manual.

Annex 2

Cover Page to be used for the Circulation of the SIDS Initial Assessment Reports

COVER PAGE
SIDS Initial Assessment Report
for
_th SIAM

(Place, date)

Chemical Name:

CAS No:

Sponsor Country:

National SIDS Contact Point in Sponsor Country:

HISTORY:

SIDS Dossier and Testing Plan were reviewed at the SIDS Review Meeting or in SIDS Review Process on (date), where the following SIDS Testing Plan was agreed:

no testing ( )
testing ( )

(If "testing" is marked, the test(s) should be identified.)

(If the SIAR was discussed at a previous SIAM, this should be mentioned and the reason given for it being discussed again.)

COMMENTS:

(Other remarks should be written here.)

Deadline for circulation:

Date of Circulation:
(To all National SIDS Contact Points and the OECD Secretariat)

Annex 3

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	
CHEMICAL NAME	
STRUCTURAL FORMULA	

CONCLUSIONS AND RECOMMENDATIONS

[The summary of properties and effects of the chemical and the result of the assessment on potential risk, and recommendations related to further work or action, as appropriate, together with the reasons which support it]

Annex 4

FULL SIDS SUMMARY

CAS NO:		SPECIES	PROTOCOL	RESULTS
PHYSICAL-CHEMICAL				
2.1	Melting Point			°C
2.2	Boiling Point			°C (at kPa)
2.3	Density			kg/m^3
2.4	Vapour Pressure			kPa at °C
2.5	Partition Coefficient (Log Pow)			
2.6 A.	Water Solubility			mg/l at °C
B.	pH			at °C
	pKa			
2.12	Oxidation: Reduction Potential			mV
ENVIRONMENTAL FATE AND PATHWAY				
3.1.1	Photodegradation			In air $T_{1/2}$ = hour
3.1.2	Stability in Water			$T_{1/2}$ = min
3.2	Monitoring Data			In air = mg/m^3 In surface water = mg/l In soil/sediment = mg/g In biota = mg/g
3.3	Transport and Distribution		Calculated (Fugacity Level 1 type)	In Air % In Water % In Sediment % In Soil % In Biota %
			(local exposure)	
3.5	Biodegradation			
ECOTOXICOLOGY				
4.1	Acute/Prolonged Toxicity to Fish			LC_{50} (24 hr) = mg/l, LC_{50} (48 hr) = mg/l, LC_{50} (72 hr) = mg/l, LC_{50} (96 hr) = mg/l
4.2	Acute Toxicity to Aquatic Invertebrates *Daphnia*			EC_{50} (24 hr) = mg/l, EC_{50} (48 hr) = mg/l,
4.3	Toxicity to Aquatic Plants e.g. Algae			EC_{50} (hr) = mg/l NOEC (hr) = mg/l
4.5.2	Chronic Toxicity to Aquatic Invertebrates (*Daphnia*)			EC_{50}s (d) = mg/l (Reproduction) EC_{50}s (d) = mg/l (Growth) LC_{50}s (d) = mg/l NOECs (d) = mg/l
4.6.1	Toxicity to Soil Dwelling Organisms			LC_{50} (d) = mg/Kg NOEL (d) = mg/Kg
4.6.2	Toxicity to Terrestrial Plants			EC_{50} (d) = mg/Kg, LC_{50} = mg/Kg EC_{50} (d) = mg/Kg, LC_{50} = mg/Kg EC_{50} (d) = mg/Kg, LC_{50} = mg/Kg
(4.6.3)	Toxicity to Other Non-Mammalian Terrestrial			LD_{50} (hr) = mg/Kg

CAS NO:		SPECIES	PROTOCOL	RESULTS
	Species (Including Birds)			
	TOXICOLOGY			
5.1.1	Acute Oral Toxicity			LD_{50} = mg/Kg
5.1.2	Acute Inhalation Toxicity			LC_{50} = mg/m^3
5.1.3	Acute Dermal Toxicity			LD_{50} = mg/Kg
5.4	Repeated Dose Toxicity			NOEL = mg/Kg
5.5	Genetic Toxicity In Vitro			
A.	Bacterial Test (Gene mutation)			+ or - (With metabolic activation) + or - (Without metabolic activation)
B.	Non-Bacterial In Vitro Test (Chromosomal aberrations)			+ or - (With metabolic activation) + or - (Without metabolic activation)
5.6	Genetic Toxicity In Vivo			+ or -
5.8	Toxicity to Reproduction			NOEL =mg/Kg (General toxicity) NOEL =mg/Kg (Repro. Tox. parental) NOEL =mg/Kg (Repro. Tox. F1 generation)
5.9	Developmental Toxicity/ Teratogenicity			NOEL =mg/Kg (General toxicity) NOEL =mg/Kg (Pregnancy/litter) NOEL =mg/Kg (Foetal data)
5.11	Experience with Human Exposure			

[Note] Data beyond SIDS requirements can be added if the items are relevant to the assessment of the chemical, e.g. corrosiveness/irritation, carcinogenicity.